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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/639,273	08/15/2000	Michael A. Innis	991.001	1822

27476 7590 10/21/2002

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EXAMINER	
LAZAR WESLEY, ELIANE M	
ART UNIT	PAPER NUMBER

1646

DATE MAILED: 10/21/2002

12/

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/639,273

Applicant(s)

Innis

Examiner

Eliane Lazar-Wesley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 29, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 7 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3,4 6) ☐ Other:

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### DETAILED ACTION

- 
1. The amendment filed July 29, 2002 has been entered.

The executed declaration filed July 31, 2002, has been considered.

Claim 7 (amended) is pending and under consideration.

New rejections apply.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is to an isolated and purified biologically active TFP1. The claim is in product-format. However, the claim is confusing , as it recites “ ...TFP1... according to a method comprising...”. It seems that Applicants intend to claim TFP1 made according to a method comprising ... , and that a word or link is missing between the words “TFP1” and “according”.

Furthermore, the claim is confusing and/or incomplete, as the preamble is to isolated and purified TFP1, while the method steps lead to the the production of an ubiquitin-TFP1 fusion protein. It is not clear if Applicants intended to claim the fusion protein as being the biologically active TFP1, or if they have omitted the cleavage of ubiquitin from the TFP1.

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***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Wun et al., Thrombosis and Haemostasis 68: 54-59, 1992, or Nordfang et al., Biochemistry 30: 10371-6, 1991.

The claim is to TFP1, and is in product-format. The claim is in product-format, and as such, it is the novelty and patentability of the instantly claimed product that need to be established and not that of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, USPQ (CCPA 1976).

Wun teaches, at page 56, col.2, that the activity of TFP1 expressed and purified from C127 cells, BHK cells and CHO cells have similar factor Xa inhibitory activity.

Nordfang teaches, at page 10371, col.2, that TFP1 expressed in and purified from C127 has similar anticoagulant activity to TFP1 expressed in and purified from BHK cells.

Applicants, in their declaration, at page 2, § 12, disclose that the activity of TFP1 expressed in and purified from *Saccharomyces cerevisiae* as described in the specification, is similar to the activity of TFP1 expressed and purified from BHK cells, is also similar to the activity of TFP1

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expressed and purified from *E. Coli*, and is also similar to the activity of TFP1 expressed and purified from C127 cells.

It appears therefore, absence evidence of the contrary, that the instantly claimed TFP1 is identical to the TFP1 described in Wun or Nordfang, and the claim is anticipated.

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.


Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

October 17, 2002

*ELW*

  
YVONNE EYLER, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600